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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,841	04/20/2004	Stephanie M. Kladakis	022956-0259	5305

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EXAMINER	
WOLF, MEGAN YARNALL	
ART UNIT	PAPER NUMBER
3738	

NOTIFICATION DATE	DELIVERY MODE
06/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No.	Applicant(s)	
	10/828,841	KLADAKIS ET AL.	
	Examiner	Art Unit	
	Megan Wolf	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-23,25 and 27-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-23,25 and 27-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/08 has been entered.

Response to Arguments

2. Applicant's arguments filed 11/13/08 have been fully considered. Arguments regarding the rejections of claims 1, 2, 4-8, and 10-17, pursuant to 35 U.S.C.102 (b) as being anticipated by Malaviya '797 are not persuasive. Applicant argues that the covers of Malaviya are only used as a cover for the scaffold disposed therebetween and not for "communicating biological materials to a tissue defect in the meniscus". However, the device of Malaviya is formed from the same materials as Applicant's invention. Malaviya teaches that ECM, the material used to form both the covers, analogous to the conduit flap, and the scaffold, is used to provide a scaffold for tissue repair and regeneration and has a three-dimensional structure and biochemical composition that attracts host cells and supports tissue remodeling (par.5). Clearly this material, which may form the cover/flap as well as the scaffold, functions to communicate biological materials. Further, because the covers completely cover the scaffold and the scaffold is expected to attract hosts cells and support tissue remodeling, the covers must allow host cells

and fluids into the space that holds the scaffold which is in the location of the tissue defect in the meniscus and therefore communicate biological materials otherwise meniscal regeneration could not occur. For example, Malaviya teaches that the implant material, including that used for the covers, should be toughened to withstand forces in the joint and at the same time "must be porous enough to permit remodeling" (par.13). Regarding Applicant's arguments directed to the intended use of the device, the examiner has not ignored the functional limitation, however, because the device of Malaviya is capable of contacting the tibial surface and extending to the synovium during use the rejection is proper. Structurally, the device of Malaviya anticipates the claimed device and specifying where it is to be used does not distinguish the invention from the prior art.

3. All other arguments are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 4-8, and 10-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Malaviya et al. 2003/0036797.

Re claims 1 and 2, Malaviya discloses a biocompatible meniscal repair device, comprising a biocompatible tissue repair scaffold 60 adapted to be placed in contact with a defect in a meniscus and a cell growth conduit flap 58,64 attached to the tissue

repair scaffold (figs. 8-16,22-55,63,64), the cell growth conduit flap capable of contacting a tibial surface, extending to the synovium, and communicating biological materials, including cells and nutrients, to a tissue defect in the meniscus (pars.13, 19, 148).

Re claim 4, ECM is bioabsorbable.

Re claims 5 and 6, see par.182.

Re claims 7, 8, and 10, see par.36.

Re claim 11, Malaviya discloses that viable tissue is disposed within the scaffold (biologically derived agents, par.159 - the agents can be tissue as described in par.33). It is inherent that the tissue would integrate with the native tissue.

Re claims 12 and 13, Malaviya discloses that the scaffold can contain within it bioactive agents (par.159) including growth factors or other agents that stimulate cell growth (par.32).

Re claim 14, the cell growth conduit flap and scaffold can be formed from a single piece, as they both can be made from the same large sheet of ECM material and cut as desired to form the specific parts. The process by which the device is made is not germane to the issue of patentability of the device itself.

Re claims 15-17, figs. 33-35 show that the flap and scaffold are oriented together such that they are substantially perpendicular. Figures 55, 63, and 64 show the scaffold and flap oriented with respect to each other such that they may be considered to form shapes of a "T" or "L".

Re claim 18, all figures show that the flap is less thick than the scaffold.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 9, 19, and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malaviya et al. 2003/0036797.

Re claims 9 and 32, Malaviya discloses that the scaffold and flap can include glycolide and L-lactide as explained above with respect to claims 7 and 8. Malaviya also discloses that any copolymer used in implants can be utilized (par.36). Malaviya does not specifically state that this device uses the copolymer of glycolide and L-lactide, however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the material with the copolymer of glycolide and L-lactide, as it is well known in the art to use the copolymer of glycolide and L-lactide and Malaviya states that copolymers can be used.

Re claim 19, Malaviya disclose the invention substantially as claimed and as discussed above. Malaviya also discloses that the covers may have a density in the range of 61-933 mg/cc and that the properties of the covers may be varied depending on the process conditions. While Malaviya does not disclose that the density of the covers is in the range of about 150mg/cc to 350mg/cc, the range of Malaviya includes the claimed range and it has been held that it is not inventive to discover the optimum or workable ranges by routine experimentation and would be an obvious extension of prior

art teachings (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A).

Re claims 30-33 see the rejections of claims 7-10 above.

8. Claims 21, 25, 27, 38, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malaviya et al. 2003/0036797 in view of Vallee et al. 4,952,404. Malaviya discloses the invention substantially as claimed and as discussed above, and further discloses the step of fixing the device in position (figs. 33, 38, 40, 41). Malaviya also discloses that the peripheral rim of the meniscus at the menisco-synovial junction is highly vascular (par.134) and that regeneration is encouraged from the radially outer portions of the device to the inner portions of the device where the native tissue is less vascularized (par.24). However, Malaviya does not specifically disclose the step of positioning a cell growth conduit flap in contact with the synovium.

Vallee teaches a method of promoting healing of meniscal tissue, in the same field of endeavor, and teaches that it is known that meniscal tears may be healed if they communicate with the synovial membrane (col.1, ll.15-19).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the placement of the device of Malaviya such that the covers contact the more vascularized synovium in order to promote healing of the meniscus as taught by Vallee.

9. Claims 22, 23, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malaviya et al. 2003/0036797 in view of Vallee et al. 4,952,404 as applied to claims 21 and 25 above, and further in view of Li et al. 4,790,819. Malaviya

discloses the invention substantially as claimed and as discussed above but does not disclose the step of rasping the meniscus or synovium before positioning the cell growth conduit flap.

Li discloses in the background of the invention, first paragraph, that the initial phase in wound repair is a fibrin clot. They further state that this is absent in meniscal tears, and as such the synovium and meniscus are regularly rasped in surgical procedures to channel the blood supply into the area to be able to form a clot (therefore the step would be before positioning any devices in the tear, as it should be the initial phase of the healing).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the step of rasping the meniscus and synovium before placing the cell growth conduit flap in position in view of the teaching of Li, in order to provide an increased blood supply to help promote wound repair.

10. Claims 20 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malaviya et al. 2003/0036797 in view of Schwartz et al. 6,468,314.

Re claim 20, Malaviya discloses the invention substantially as claimed and as discussed above and Malaviya further discloses that the material that forms all parts of the device should be porous enough to permit remodeling (par.13). However, Malaviya does not specifically teach a void volume in the range of about 50-95%.

Schwartz teaches a cartilage repair device, in the same field of endeavor, wherein the void volume is at least 95% for the purpose of allowing for an invasion of cells to regenerate the articular cartilage.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify porous device of Malaviya to have a void volume greater than 95% as taught by Schwartz in order to allow for cells to penetrate the device and regenerate the meniscus. Regarding the claimed void volume range of about 50-95% it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A). Therefore, it would have been obvious to modify the void volume of Malaviya based on the general conditions taught by Schwartz.

Re claims 34-37, see the rejection of claims 7-10 above.

11. Claims 39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malaviya et al. 2003/0036797 in view of Vallee et al. 4,952,404 as applied to claims 21 and 25 above, and further in view of Schwartz et al. 6,468,314. Malaviya in view of Valle discloses the invention substantially as claimed and as discussed above and Malaviya further discloses that the material that forms all parts of the device should be porous enough to permit remodeling (par.13). However, Malaviya in view of Vallee does not specifically teach a void volume in the range of about 50-95%.

Schwartz teaches a cartilage repair device, in the same field of endeavor, wherein the void volume is at least 95% for the purpose of allowing for an invasion of cells to regenerate the articular cartilage.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify porous device of Malaviya to have a void volume greater than 95%

as taught by Schwartz in order to allow for cells to penetrate the device and regenerate the meniscus. Regarding the claimed void volume range of about 50-95% it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A). Therefore, it would have been obvious to modify the void volume of Malaviya based on the general conditions taught by Schwartz.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Wolf whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738